UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,774	03/22/2004	Gail K. Naughton	A0831.70013US04	9926

23370 7590 05/15/2008

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
05/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,774	NAUGHTON, GAIL K.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-22 and 30-44* is/are pending in the application.

4a) Of the above claim(s) *16-22 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims in the application are 16-22 and 30-44.

A response of 2/11/08 to a restriction requirement elected Group II claims 33-44 without traverse.

Claims 16-22 and 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/22/08.

Claims examined on the merits are 33-44.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support is not found in the specification for "type IV" collagen required in the claims. The specification discloses only types I and III collagens.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 2 of claim 33 "naturally secreted human collagen synthesized by cells in vitro" is uncertain as to meaning and scope. Being naturally secreted is relative and subjective. Since the collagen is secreted in vitro, the collagen is not naturally secreted since in vitro is not natural.

Claims 42-44 are unclear how the process limitations required further limit the composition of claim 33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palefsky et al (5,428,022) in view of Naughton et al

(5,032,508), and if necessary in further view of Tanagho et al (5,656,478).

The claims are drawn to an injectable composition containing a cell-free injectable formulation of naturally secreted human collagen synthesized by cells in vitro and a pharmaceutically acceptable carrier formulated for in vivo administration by injection with a syringe.

Palefsky et al disclose (col 2, lines 38-49) an injectable composition containing human placental collagen suspended in a physiologically acceptable injectable carrier that may contain lidocaine (col 2, line 48). The collagen is composed of type I and type III collagen, and the collagen is sterilized (col 2, line 64 and col 8, line 12) and may be cross-linked (col 2, line 67).

Naughton et al disclose (col 2, line 60 to col 3, line 54, paragraph bridging cols 6 and 7, col 8, line 45 to col to col 9, line 31, and col 11) culturing stromal cells comprising fibroblasts (col 9, line 15) on a framework matrix having openings of 150-220 μm (col 11, lines 33-34) to form on the framework matrix containing stromal cells cultured cells and collagen secreted by the cells (col 11, lines 50-51 and 59-60). Tissue specific cells are grown on the resultant stromal matrix containing cultured stromal cells and collagen. The tissue specific cells can be separated from the framework matrix and implanted (col 15, lines 7-15). Fibroblasts can be selected to express a desired collagen type or a mixture of stromal cells can be used to synthesize desired collagen types (col 11, lines 57-62).

Depending on the type of tissue to be cultured and the collagen types desired, the appropriate stromal cells may be selected (col 12, lines 26-29 and Table I (bridging cols 11 and 12)). For optimum growth of hematopoietic cells, the matrix should contain types I, III IV collagen (col 11, line 46).

Tanagho et al disclose a composition containing smooth muscle cells, extracellular matrix (Matrigel™) and a pharmaceutical acceptable carrier for injecting to grow smooth muscle tissue (col 7, lines 1-20).

It would have been obvious to produce collagen for use in the composition of Palefsky et al by culturing human cells in vitro that produce types I and III collagen as suggested by Naughton et al disclosing culturing in vitro cells that produce a desired type of collagen which can be types I and III collagen. Producing the collagen in vitro by culturing cells as suggested by Naughton et al would have been expected to be advantageous by eliminating the need to depend on the availability of human placenta as a source of the collagen. Collagen comprising types I and III collagen produced in vitro from human cells would have been expected to be functionally equivalent to human placental collagen. The conditions of dependent claims would have been obvious from the conditions disclosed by the references. Tanagho et al further disclose an injectable composition containing collagen (extracellular matrix), and if needed would have further suggested the present invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,284,284 B1 or claims 1-10 of U.S. Patent No. 5,830,708. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed injectable composition containing collagen would have been obvious from the composition suitable for injection containing extracellular matrix produced by the method of the claims of the patents. Extracellular matrix is formed of collagen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
5/12/08